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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Masahiro Ishikawa

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WENDEROTH, LIND & PONACK, L.L.P.

1030 15th Street, N.W.,

Suite 400 East

Washington, DC 20005-1503

EXAMINER

TSAY, MARSHA M

ART UNIT

PAPER NUMBER

1656

NOTIFICATION DATE

DELIVERY MODE

05/12/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com

coa@wenderoth.com

Office Action Summary	Application No. 10/532,678	Applicant(s) ISHIKAWA ET AL.	
	Examiner Marsha Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 9, 2010, has been entered.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 5-8 are canceled. Claims 1-4, 9 are currently under examination.

Priority: The request for priority to JAPAN 2002-328243, filed November 12, 2002, is acknowledged.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitoh et al. (US 6638562; previously cited) in view of Howard et al. (US 4368151; IDS 12.13.05, previously cited). Claim 1 has been given its broadest and most reasonable interpretation, i.e. a process for producing soybean protein in an industrial scale consisting essentially of heating a soybean

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protein solution under acidic conditions, and then fractionating it (ionic strength 0.02-0.2, pH 4.5-5.6) into a soluble fraction and an insoluble fraction.

In Example 2, Saitoh et al. disclose a process for producing soybean protein comprising heating a solution of defatted-soybean milk at pH 5.9 to 40°C (col. 9 lines 10-14). Saitoh et al. further disclose that phytase was added to the soybean protein solution and fractionated to obtain an insoluble fraction and a soluble fraction (col. 9 lines 16-20). Saitoh et al. disclose a 7S and an 11S globulin protein with a phytic content of 0.05% weight of protein (col. 9 line 18, lines 30-35). Saitoh et al. do not teach "fractionation conditions" at an ionic strength of 0.02 and pH of 4.5-5.6.

Howard et al. disclose a method for fractionating 11S protein from 7S protein comprising a step of providing an ionic solution strength in the range from about 0.0005u to about 0.2u and at a pH range 5.3-6.3 (col. 11 lines 50-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Saitoh et al. by using the fractionation conditions (ionic strength range 0.0005 to 0.2, pH 5.3) of Howard et al. during the fractionation process of Saitoh et al. in order to obtain a soluble fraction and an insoluble fraction (claims 1-4, 9). The motivation to do so is given by Howard et al., which disclose that said fractionation conditions are successful in precipitating 11S protein from 7S protein.

Applicants are reminded that, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim

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was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.) Also, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.").

Regarding the element "in an industrial scale" recited in claim 1, it should be noted that Saitoh et al. disclose that their process for producing soybean protein can be carried out in an industrial scale (col. 3 lines 29-30).

Regarding the use of "consisting essentially of" language recited in claim 1, MPEP 2111.03 notes that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). In this instance, while the method of Saitoh et al. in view of Howard et al.

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may include additional elements and/or steps, said additional elements and/or steps do not materially affect the process of obtaining the soybean protein.

Regarding claim 9, while the claim recites a process for improving a separation-precipitation rate of an insoluble fraction for separating a soluble fraction containing 7S globulin from the insoluble fraction, it should be noted that since the steps recited in claim 9 are the same and/or within the scope of Saitoh et al. in view of Howard et al., this process would be achieved anyways even if not explicitly recognized by Saitoh et al. in view of Howard et al. The fact that Applicant performs the process of Saitoh et al. in view of Howard et al. for a different purpose (i.e. to improve a separation-precipitation rate) does not alter the conclusion that the use of the process in the prior art would be prima facie obvious from the purpose disclosed in the references (i.e. to produce a soybean protein). Further, the "separation-precipitation" rate appears to be related to the heating conditions and/or the ionic strength (specification p. 23 Table 1, p. 25 Table 3), which are therefore, the fractionation conditions. Since Saitoh et al. in view of Howard et al. disclose the instant "fractionation conditions" of an ionic strength of 0.02 and pH of 4.5-5.6, improving the "separation-precipitation" rate would therefore be expected over Saitoh et al. in view of Howard et al.

In their remarks, Applicants assert that (1) the adjustment of ionic strength is not carried out in Saitoh et al. (2) The present invention provides the excellent and unexpected result of improving the "separation-precipitation rate" of 11S. Saitoh et al. fail to teach or suggest adjustment of an ionic strength, as required by Applicants' claims. This deficiency was previously acknowledged by the Examiner, who relied upon Howard et al. as allegedly

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remedying this deficiency. As discussed in previous responses, Howard et al. disclose a method of separating 7S globulin and 11S globulin in the presence of sulfite ion. Specifically, the method comprises: (A) providing to a solution a sufficient amount of: **(i) from about 0.05 mM to about 5.0 mM sulfite ion; and (ii)** water-soluble salt to provide an ionic solution strength ranging from about 0.0005u to about 0.2u; (B) precipitating at least a major weight of said 11S protein from said solution within the pH 5.3-6.3 range; and (C) recovering the precipitated 11S protein from said solution. (Please see claim 1 of Howard et al.). Thus, the presence of sulfite ion is essential for Howard et al. to provide the desired ionic solution strength. Accordingly, the inclusion of sulfite ion would materially affect the basic and novel characteristics of Applicants' claimed method, and is thus excluded by the "consisting essentially of" language of the present claims. Therefore, one of ordinary skill in the art would not combine the teachings of Saitoh et al. and Howard et al., and arrive at Applicants' claimed invention, particularly since the Howard et al. method employs a step which is specifically excluded by Applicants' claims.

Applicant's arguments have been fully considered but they are not persuasive.

(1) Reply: The deficiency of Saitoh et al. to disclose the instant "fractionation conditions" of an ionic strength of 0.02 and pH of 4.5-5.6 is remedied by the Howard et al. reference.

(2) Reply: As noted above, regarding the use of "consisting essentially of" language recited in claim 1, MPEP 2111.03 notes that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). In this instance, while the method of Saitoh et al. in

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view of Howard et al. may include additional elements and/or steps (i.e. using sulfite ion), said additional elements and/or steps do not materially affect the process of obtaining the soybean protein. It should be noted that instant claim 1 recites a process for producing a soybean protein, which is also the process of Saitoh et al. in view of Howard et al., i.e. to produce a soybean protein.

Regarding Applicants' remarks on the present invention's unexpected effect of improving the "separation-precipitation" rate of 11S, it should be noted that the "separation-precipitation" rate appears to be related to the heating conditions and/or the ionic strength (specification p. 23 Table 1, p. 25 Table 3), which are therefore, the fractionation conditions. Since Saitoh et al. in view of Howard et al. disclose the instant "fractionation conditions" of an ionic strength of 0.02 and pH of 4.5-5.6, Applicants' effect of improving the "separation-precipitation" rate would therefore be expected over Saitoh et al. in view of Howard et al.

For at least these reasons, the claims remain rejected under 103(a).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marsha Tsay/
Primary Examiner, Art Unit 1656

May 7, 2011